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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,911	01/07/2002	Frank E. Manning	GUID.038US01	4087

7590

09/16/2003

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/16/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/041,911

Applicant(s)

MANNING ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

The election requirement set forth in the action dated 5/12/03 has been withdrawn in response to applicant's election with traverse filed 6/12/03.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pre-stress line on the inner sheath (claim 4) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 5 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,592,581 to Bowe.

In regards to claims 1, 5 and 15, Bowe discloses applicant's claimed invention including an outer sheath having an open lumen and a pre-shaped distal end (Col. 9, lines 15 – 19); an inner sheath having an open lumen, the inner sheath disposed within the open lumen of the outer sheath,

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the inner sheath being axially rotatably and longitudinally translatable relative to the outer sheath, a distal end of the inner sheath conforming to a shape of the outer sheath when the inner sheath is retracted, and the distal end of the inner sheath assuming a pre-formed shape when the distal end of the inner sheath is extended beyond the distal end of the outer sheath (Col. 9, line 61 – Col. 10, line 5); a steering tendon along the outer sheath, a distal end of the tendon connected to a distal tip of the outer sheath (Col. 10, lines 53 – 57); a guide handle connected to a proximal end of the outer sheath (Col. 10, line 56); an a steering mechanism disposed on the handle, the steering mechanism connected to a proximal end of the tendon and providing a pulling force on the steering tendon to adjust a shape of the preshaped distal end of the outer sheath. Bowe discloses at least one electrode on the distal end of the inner sheath (Col. 8, lines 15 – 17) and at least one electrical conductor coupled to the at least one electrode, the conductor being disposed within the inner sheath. Bowe discloses the outer sheath having a second lumen, the steering tendon disposed within the second lumen of the outer sheath (Col. 10, lines 48 – 50).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,592,581 to Bowe as applied to claim 1 above, and further in view of U.S. Patent No. 5,462,527 to Stevens-Wright et al.

In reference to claim 2, Bowe discloses a steering mechanism, but fails to disclose the steering mechanism being pivotably connected to the guide handle. Stevens-Wright et al. discloses a catheter guiding device wherein the steering mechanism (92) is pivotably connected to the guide handle. It would have been obvious to one having ordinary skill in the art to replace the steering mechanism as disclosed by Bowe to include a pivotably connected steering mechanism in that the steering mechanism disclosed by Bowe and the pivotably connected steering mechanism as taught by Stevens-Wright et al. are functionally equivalent and therefore interchangeable.

6. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,592,581 to Bowe as applied to claim 1 above, and further in view of U.S. Patent No. 6,574,512 to Zhang et al.

7. In reference to claims 3 and 4, Bowe fails to disclose a longitudinally disposed pre-stress line extending from the proximal end to the distal end of the outer or inner sheath. However, Zhang et al. discloses a lead introducer having a longitudinally disposed pre-stress line extending from the proximal end to the distal end (Col. 9, lines 38 – 55). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Bowe to include pre-stress lines as taught by Zhang et al. to aid in the removal of the device from the vasculature.

8. Claims 6 and 11 - 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,592,581 to Bowe as applied to claim 1 above.

9. In reference to claim 6, Bowe discloses at least one electrode on the distal end of the inner sheath (Col. 8, lines 15 – 17) and at least one electrical conductor coupled to the at least one electrode, the conductor being disposed within the inner sheath. However, Bowe fails to disclose the at least one electrode being on the distal end of the outer sheath. However, it would have been

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an obvious engineering design choice to place the electrode as disclosed by Bowe on the outer sheath in that the electrode would perform the same function being placed on the outer sheath as well as the inner sheath.

In reference to claims 11 and 12, Bowe discloses the inner and outer sheaths conforming to predetermined shapes. Bowe discloses that the device can be made to accommodate any predetermined shape (Col. 12, lines 37 – 40). A change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). In the present case it would have been within the skill of the art to modify the predetermined shape as disclosed by Bowe to include any shape as desired.

In reference to claims 13 and 14, Bowe discloses the tendon being disposed along the outer sheath, but fails to disclose the tendon being on outer surface of the sheath or within the open lumen of the sheath. However, due to the lack of criticality in the specification for the positioning of the steering tendon, it would have been obvious to one having ordinary skill in the art at the time the device was made to position the tendon on the surface or within the interior of the lumen as desired.

10. Claims 7 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,592,581 to Bowe as applied to claim 1 above, and further in view of U.S. Patent No. 6,533,770 to Lepulu et al.

In reference to claims 7 – 10, Bowe fails to disclose an occlusion device connected to the inner or outer sheath and at least one pressure sensing device connected to the inner or outer sheath. However, Lepulu et al. discloses a guidewire having an occlusion device connected to the distal end of the inner sheath and a pressure sensing device located within the inner sheath (Col. 17, lines 26 – 35). It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify the device as disclosed by Bowe to include an occlusion device and a pressure sensing device as taught by Lepulu et al. in order to further the diagnostic capabilities of the device. Furthermore, placing the occlusion device and the pressure sensing device on the inner or outer sheath is a design consideration within the skill of the art.

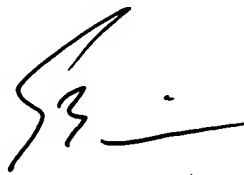
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-308-0758 for regular communications and (703)-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.


JMLF
September 8, 2003


ERIC F. WINAKUR
PRIMARY EXAMINER